Toshiba America Medical Systems, Inc.
Pre-market Notification 510(k)
CSLV-001A, Lung Volume Analysis

AUG 17 2012

510(k) Summary

Date:	December 16, 2011
Manufacturer:	Toshiba Medical Systems Corporation 1385 Shimoishigami, Otawara-shi, Tochigi-ken, 324-8550, Japan
Initial Importer/Distributor: **Address:**	Toshiba America Medical Systems, Inc. P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Contact:	Paul Biggins, Director Regulatory Affairs (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	CSLV-001A, Lung Volume Analysis
Common Name:	Scanner, Computed Tomography, X-Ray
Classification:	90-JAK
Regulatory Class:	II (per 21 CFR 892.1750)
Performance Standard:	None
Predicate Device(s):	Siemens Healthcare; InSpace 4D (InSpace Lung Parenchyma), k071513
Reason for Submission	New Device

Description of this Device:

The CSLV-001A, Lung Volume Analysis is a post-processing software that provides work flow enhancements by providing automated measurement and extraction capabilities to the clinician. This software employs image data sets from thoracic studies to perform its functions, no additional radiation exposure is required.

Toshiba America Medical Systems, Inc.
Pre-market Notification 510(k)
CSLV-001A, Lung Volume Analysis

Summary of Intended Uses:

The Lung Volume Analysis can be used to support the physician in the diagnosis and documentation of chest diseases, e.g. when examining the pulmonary tissue (i.e. lung parenchyma) in CT thoracic datasets. Evaluation tools (3D segmentation & isolation of subcompartments, volumetric analysis) and reporting tools are combined with a dedicated workflow. This software application can be used with standard non-contrast-enhanced chest volume acquisitions.

When used by a qualified physician, a potential application is to determine the course of treatment.

Substantial Equivalence:

This device is substantially equivalent to the predicate devices which are commercially available at this time in that it offers the same or similar functions as the predicate device.

Siemens Healthcare; InSpace 4D (InSpace Lung Parenchyma), k071513

Summary of Testing:

This device was tested using an electronic phantom, LungMan Phantom™, and image data sets of the chest. Statements related to the accuracy of the software are contained in the user information based upon this testing.

Safety:

This device is designed and manufactured under ISO-13485 to include meeting the requirements of 21 CFR 820. Additionally this system is designed and manufactured in conformance with the appropriate IEC safety standards. This includes the employment of risk mitigation during the development of this device.

Radiation safety is assured by meeting the associated requirements of 21 CFR 1020. This information is provided to the FDA in compliance with the required CT product reports.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2012

Toshiba Medical Systems Corporation, Japan
% Mr. Paul Biggins
Director, Regulatory Affairs/U.S. Agent
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K113715
Trade/Device Name: CSLV-001A Lung Volume Analysis
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 7, 2012
Received: August 8, 2012

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113715

Device Name: CSLV-001A Lung Volume Analysis

Indications for Use:

The Lung Volume Analysis can be used to support the physician in the diagnosis and documentation of chest diseases, e.g. when examining the pulmonary tissue (i.e. lung parenchyma) in CT thoracic datasets. Evaluation tools (3D segmentation & isolation of subcompartments, volumetric analysis) and reporting tools are combined with a dedicated workflow. This software application can be used with standard non-contrast-enhanced chest volume acquisitions.

When used by a qualified physician, a potential application is to determine the course of treatment.

Prescription Use ☑ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113715